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NOTIFICATION OF ELECTION

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International filing date (day/month/year) 18 March 1998 (18.03.98)	**Priority date** (day/month/year) 19 March 1997 (19.03.97)
Applicant JACKSON, James, Richard	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

07 October 1998 (07.10.98)

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2. The election [X] was

[ ] was not

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(54) Title: RECORDING ASSAY DEVICE

(57) Abstract

The invention herein described relates to an assessment device comprising an assay part and a detachable recording part. The assessment device facilitates the rapid assaying and processing of tissue/fluid samples by healthcare workers. Also, advantageously, the result of the assay is only apparent to the healthcare worker after interrogation of the recording part at a processing facility.

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RECORDING ASSAY DEVICE

The invention herein described is an assay and recording means for use in, particularly but not exclusively, the diagnosis and/or analysis of tissue and/or fluid samples taken from a human or animal which comprises an assay part and a detachable data recording part.

The analysis of tissue or fluid samples is of crucial importance if the appropriate diagnosis of a patient is to be made by a healthcare worker. Also, there are numerous conditions that need constant monitoring to maintain the correct treatment regime. For example,and not by way of limitation, infectious disease (including HIV), diabetes, osteoporosis, tumour cell markers, reproductive endocrinology, thyroid disease haematology, therapeutic drugs, drugs of abuse, cardiac disease, treatment monitoring clinical trials assessment.

Also, it is apparent that the human genome project will identify genes that are involved, either directly or indirectly, in a number of inherited genetic diseases. Clearly it will be important to efficiently process this genetic information to offer appropriate treatment and/or counselling to individuals that are genetically predisposed to certain diseases. It is highly likely that both conventional processing facilities (i.e. to deal with monitoring various metabolites as described above) and also new means to efficiently process genetic information will be required to deal with expanding healthcare.

It is also apparent that there are situations where adequate medical advice/treatment is either unavailable or not easily accessible to individuals. For example, and not by way of limitation, armed forces personnel on active

service in war zones, armed forces personnel on active service in non-war situations but are effectively remote from medical assistance (i.e. ships, submarines etc), individuals that farm in remote areas (i.e. Australian outback, Africa), individuals who work for long periods away from adequate medical assistance (i.e. workers on oil/gas installations, research workers in polar or tropical regions, merchant navy personnel). It is important that these individuals receive rapid and reliable diagnosis of their condition so that the correct treatment is administered.

Also a number of the planets inhabitants live on remote islands that do not have extensive medical support and may require a rapid means to diagnose a condition that obviates the need for the individual to visit a mainland hospital or alternatively for a doctor to visit the individual on the island to remove samples for analysis.

On a less extreme note there are examples where, although a hospital is local to an individual, there may be extenuating circumstances that prevent or make difficult the attendance of the individual at an outpatients clinic to give samples for testing. Those suffering, for example, from bronchitis or emphysema, the elderly and infirm and any other individuals who would find a trip to their local hospital physically stressful and potentially hazardous. Currently, patients of this type can have home visits to monitor their condition. However, these are expensive and time consuming since some of a healthcare workers effective time is spent travelling to the patients home.

In addition it may be desirable to analyse the recorded result of an assay by a healthcare worker at a data processing site remote from the patient rather that rely on the patient to record and report the result of the test. There are

certain patients, (i.e. those suffering from mental disorders e.g. depression schizophrenia), where it may be desirable to keep the results of an assay secret until the healthcare worker can process the data to enable the correct diagnosis to be determined. It is well known in the art that patients can wilfully interfere with an assay to give an erroneous measure of the particular variable monitored by the assay. If the recording device merely records the information for subsequent processing and analysis this possibility is minimised.

This has particular relevance in clinical trial assessment of candidate drugs to provide a non-biased data collection means from treated and placebo groups to ensure a reliable assessment of drug efficacy is obtained.

It is therefore an object of the invention to provide a generic assay and a recording device which efficiently monitors an individuals health status.

It is a further object of the invention to provide an assay and recording means wherein said recording means is detachable from said assay means.

According to a first aspect of the invention there is provided an assessment device comprising an assay part and a recording part wherein said recording part is detachable from said assay part.

In a preferred embodiment of the invention said assessment device is selectively sized and shaped to facilitate handling and transport of the assessment device to the relevant processing facility.

In a preferred embodiment of the invention said recording device is selectively sized and shaped to facilitate handling and transport of the recording device to the relevant processing facility.

The above embodiment relates to a recording device that is sufficiently small and light to be transported via a conventional transport means for example, and not by way of limitation, the postal service or courier service.

In an alternative preferred embodiment of the invention said recording device may be adapted to facilitate data transfer via electronic means.

It will be apparent that in subsequent years the use of the Internet will become more widely accessible to the general public. The recording device may therefore be adapted to interface with a personal computer within an individuals home or place of work. Data transfer ideally will be encrypted to prevent third party access and decoded at a processing facility via responsible healthcare worker.

In yet a further preferred embodiment of the invention said detachable recording device is provided in retro-fit form, i.e. it may be desirable to adapt a pre-existing assay device to receive a recording part to enable data recording and storage.

It will be apparent from the above embodiment that the assessment device may be manufactured as a single unit. Alternatively, via suitable adaptation, said recording part or device may be attached to an existing assay part or device to enable data recording.

In yet a further preferred embodiment said recording device is a micro processor or other similar electronic device. Alternatively, said recording device is photographic, comprising, for example, a photographic emulsion, the stored images of which are developed at a processing facility.

It will be apparent that the above means for recording data from the assay can be processed by conventional means at the processing facility by down loading the stored information/images at a computer by a healthcare worker. Alternatively, if the worker has access to the internet the data/images can be transferred electronically from the individual to the healthcare worker at the processing facility.

In yet a further preferred embodiment of the invention there is provided an assessment device comprising an assay part with at least one sample application well.

Reference herein to sample application well is intended to encompass any recepticle, recess, indentation, or well into which a tissue/fluid sample can be placed.

Reference herein to a fluid sample is intended to include both a liquid and a gas sample, for example, urine, blood, saliva, mucous, pus, semen,breathe.

In a preferred embodiment of the invention said recording assay device is characterised by multiple sample application wells. Ideally, one or more of said well or wells is provided, suitably impregnated, with materials for sampling said fluid sample.

In yet a further preferred embodiment of the invention said assay part is adapted by the provision of at least one primary conduit in fluid connection with said sample application well. Ideally said primary conduit contains assay reagents in some instances suitable for diluting said sample fluid. More preferably further still, said conduit is suitably sized to facilitate capillary flow of said sample fluid therethrough.

In yet a further preferred embodiment of the invention said assay part is further adapted by the provision of at least one secondary conduit which is in fluid connection with one or more of said sample application wells; and which is ideally also adapted to provide for capillary flow therethrough. Preferably further still said secondary conduit contains assay reagents, ideally of a nature different to the assay reagents in said primary conduit but most suitably compatable therewith so as to provide, in total, for the complete and selected assaying of said fluid sample as it flows through either or both of said primary/ secondary conduits.

In yet a further preferred embodiment of the invention at least one control or calibration is provided in the assessing device. For example, a control conduit may be provided for monitoring flow through the device. Said control conduit may optionally be providedwith assay reagents, or alternatively, the elements, to be detected by the assay inorder to produce a positive result or identification.

In yet still a further preferred embodiment of the invention there is provided an assay part provided with at least one assay conduit which is further characterised by a detection zone to facilitate the detection of the product(s) of the assay.

According to yet a further aspect of the invention there is provided a method to assay and record a tissue/fluid sample from an individual comprising;

(i) applying a sample to a sample application well of an assessment device as hereindescribed;

(ii) mixing said sample with at least primary assay reagents;and

(iii) recording the data from i-ii via the recording part.

It will be apparent to one skilled in the art that this method enables the rapid processing of an applied fluid/tissue sample within minutes of application to the sample well. This will reduce erroneous assay of samples due to sample degradation during long term storage.

It is well known in the art that assay reagents comprise, and not by way of limitation, buffers, substrates, enzymes, antibodies, co-factors, intermediary metabolites, nucleic acid. It will also be apparent that there are well known in the art means to assay various factors. For example, antibody techniques using polyclonal/monoclonal antibodies to specific epitopes (e.g. drugs, hormones, steroids, tumour specific cell surface antigens, viral/bacterial antigens) . Enzyme based techniques for monitoring, for example, glucose or cholesterol in blood plasma. Many of these techniques rely on a colour change as an indication of the presence of the desired agent(s). More recently chemiluminescent and/or fluorescent detection means are available and will be applicable to the assay recording device.

According to yet a further aspect of the invention there is provided a kit comprising; an assessment device as hereindescribed, assay reagents and

optionally protective packaging for transport of the recording device to the processing facility.

It will be apparent that the recording assay device has widespread application in the diagnosis of disease. It may also have a role in clinical trials assessment of potential therapeutic agents providing a non-biased means of collecting data from treated and placebo groups to ensure a reliable assessment of drug efficacy is obtained.

An embodiment of the invention will now be described, by example only, and with reference to the following figures wherein,

Figure 1 is a diagrammatic representation of the assay part of an assessment device;

Figure 2a is a diagrammatic representation of the internal layout of an assessment device; and

Figure 2b represents a diagrammatic representation of an external view of an assessment device

Referring to figure 1, a diagrammatic representation of an assay part of the recording assay device is shown . The assay part is characterised by the presence of a selectively sized and shaped sample application well (1) which is circular in the diagram. The sample application well (1) is in fluid contact with a primary assay reagent conduit (2). The primary reagent conduit is selectively sized to facilitate the movement of sample applied to the application well(1) by capillary flow. The primary reagent conduit contains

at least some of the reagents necessary to complete a reaction with the sample applied to the sample well (1) or begin an initial reaction with the applied sample. Additionally the reagents may represent solutions used to dilute the sample and/or primary assay reagents. A single assay well (1) is shown in the diagram. However, the device may be adapted to contain multiple application wells in fluid contact with one or more primary reagent conduits.

The primary assay reagent conduit comprises filter paper, or other suitable means, impregnated with the primary assay reagents and can comprise additionally, or alternatively, any of the following alternatives;

(i) multiple channels formed in paper or other water permeable material by impregnation with polymers to form water impermeable regions;

(ii) multiple channels formed in nitrocellulose or other water permeable diagnostic or filter membrane by impregnation with wax to form water impermeable regions;

(iii) formation of strips of water permeable material within a sheet of the material by cutting regions from a sheet of the material, in order to form multiple channels;

(iv) printing (e.g. by silk screen) of a water permeable material (e.g. nitrocellulose or other material used to make diagnostic and filter membranes) in emulsion or other fluid form onto a water impermeable surface to create channels of the water permeable material;

(v) multiple water permeable channels comprised of any material and produced by any method;

(vi) a single water permeable channel or strip comprised of any material and produced by any method. In a single channel device there would be one or more detection zones;

(vii) a channel(s) of free space, within a water impermeable structure, forming a capillary in which liquid may flow by capillary action. This technique is sometimes referred to as a "capillary flow" diagnostic device. In a single channel device there would be one or more detection zones; and

(viii) other types of channel.

In use a fresh sample applied at (1) is moved via capillary action into the primary reagent conduit. The filter paper may be hydrophilic over at least part of its area to restrict and/or concentrate the flow of sample along the primary conduit (2).

The primary reagent conduit is optionally in fluid contact with a secondary reagent conduit (3) containing secondary assay reagents. The secondary reagent conduit is selectively sized to facilitate capillary flow of sample from the primary reagent conduit. Figure 1 represents a single secondary reagent conduit. In an alternative embodiment of the invention more than one secondary reagent conduit may be present containing reagents required to complete the assay. Again capillary flow will draw the sample/primary assay reagent mix into the secondary assay conduit (3) to facilitate the reaction of secondary reagents with the sample/primary assay reagent mix. A detection zone (4) is selectively positioned to interact with the reaction mixture once all components have been mixed and the assay completed. The detection zone (4) may contain substrates necessary to allow detection of the product of the assay. Alternatively, these substrates may be incorporated in

the primary and/or secondary mix. Detection may be via a colour change or other suitable means (e.g. chemiluminescence, fluorescence emission).

Two preferred detection means are readily applicable to the assessment device;

(i) recording of an electrochemical reaction by a microprocessor or other solid-state device. Amperometric and potentiometric assay detection techniques are appropriate. This is the preferred detection system, as the removable recording system can be kept from contacting physically with any of the components of the sample by means of the electrical connection between the detection zone and the recording device, thus rendering it completely safe from infectious risk on handling, figure 2; and

(ii) recording of a photometric reaction by a photographic or other light sensitive film or device. Chemiluminescence and fluoresence are appropriate. The film and detection zone can be separated by a clear water impermeable layer which will prevent the film from contacting physically with any of the components of the sample.

Additionally other detection means include;

(iii) reflectance or transmittance photometry; production of a stable dye on a surface by biochemical or chemical reaction, including ELISA;

(iv) microparticles, including polymers, metallic and non-metallic elements and other materials;

(v) soluble coloured substances, including dyes. These would be determined by a light reflectance technique(including fluorimetry) or light transmittance technique or another technique related to any specific feature of any soluble substance used; and

(vi) other assay detection systems.

The detection is recorded and stored in a microprocessor located in the recording means, not shown in figure 1. The assay part is further adapted by the provision of a waste well (5) to store excess sample/reaction mix.

Referring to Figure 2a, an alternative embodiment of an assay part is shown diagrammatically with a detachable recording part (7). The single sample application well is shown (1) in fluid connection with a plurality of conduits (6). The conduits identified in figure 2a may contain alternate assay reagents to facilitate multiple testing of variables of the applied sample. For instance, glucose, salts, hormone levels, the detection of specific epitopes via immune reaction. The plurality of conduits (6) each contain a detection zone (4), each of which is connected to a microprocessor (8) via electrical connections (7) to facilitate interrogation of the assay in the detection zone (4). The assay recording device is also provided with a test ready indicator (9) to monitor device status thereby allowing the user to readily identify when the device has completed the assay.

Referring to Figure 2b an external diagrammatic representation of an assay/recording device is shown. The outer casing (12) is manufactured from a durable material, (e.g. reinforced plastic). The recording part is easily detached from the assay part via a perforated attachment means (11). Alternatively the assay part and recording part may be selectively attached via a clip, hasp, lock, or any suitable means to facilitate the attachment or detachment of said assay part from said recording part. In use the patient applies a sample to a sample well (1) through an application port (13). When sufficient time has lapsed to allow the assay to reach an end point the

test ready indicator (9) conveys this to the user. The user can then simply detach the recording part from the assay part and send the data to a processing facility for decoding and interrogation.

The invention therefore provides for a device that operates in a stable, reliable and reproducible manner and advantageously the results of the assay are not available to a user until further, remote, processing has occurred.

CLAIMS

1. An assessment device comprising an assay part and a recording part wherein said recording part is detachable from said assay part.

2. An assessment device according to Claim 1 wherein said assessment device and/or recording part is selectively sized and shaped to facilitate handling and transport of same to a processing facility.

3. An assessment device according to Claims 1 or 2 wherein said recording part is adapted to facilitate the transfer of data via electronic means.

4. An assessment device according to Claims 1-3 wherein said recording part is in retro-fit form.

5. An assessment device according to Claims 1-4 wherein said recording part is a micro processor.

6. An assessment device according to Claims 1-4 wherein said recording part is a photographic recording means.

7. An assessment device according to Claims 1-6 wherein said assay part is characterised by the inclusion of at least one sample application well.

8. An assessment device according to Claims 7 wherein said assay part is characterised by multiple sample application wells.

9. An assessment device according to Claim 8 wherein at least one of said sample application wells is impregnated with material(s) for sampling a fluid sample.

10. An assessment device according to Claims 7-9 wherein said assay part is provided with at least one primary conduit in fluid connection with said sample application well(s).

11. An assessment device according to Claim 10 wherein said primary conduit contains assay reagents for sampling said fluid sample.

12. An assessment device according to Claim 10 or 11 wherein said primary conduit contains reagents suitable for diluting said sample fluid.

13. An assessment device comprising a primary conduit according to Claims 10-12 wherein said primary conduit is suitably sized to facilitate capillary flow of said sample fluid therethrough.

14. An assessment device according to Claims 7-13 wherein said assay part is provided with at least one secondary conduit which is in fluid connection with one or more of said sample application wells.

15. An assessment device according to Claim 14 wherein said secondary conduit is suitably sized to facilitate capillary flow of said sample fluid therethrough.

16. An assessment device according to Claims 14 or 15 wherein said secondary conduit contains assay reagents.

17. An assessment device according to claim16 wherein said assay reagents are of a different nature to the assay reagents in the said primary conduit.

18. An assessment device according to Claim 17 wherein said assay reagents are compatible with the assay reagents of the primary conduit so as to provide, in total, for the complete and selected assaying of said fluid sample as it flows through either or both primary and/or secondary conduits.

19. An assessment device according to Claims 1-18 wherein said assessment device includes at least one control or calibration means.

20. An assessment device according to Claims 1-19 wherein said assay part is provided with at least one detection zone to facilitate detection of the product(s) of an assay.

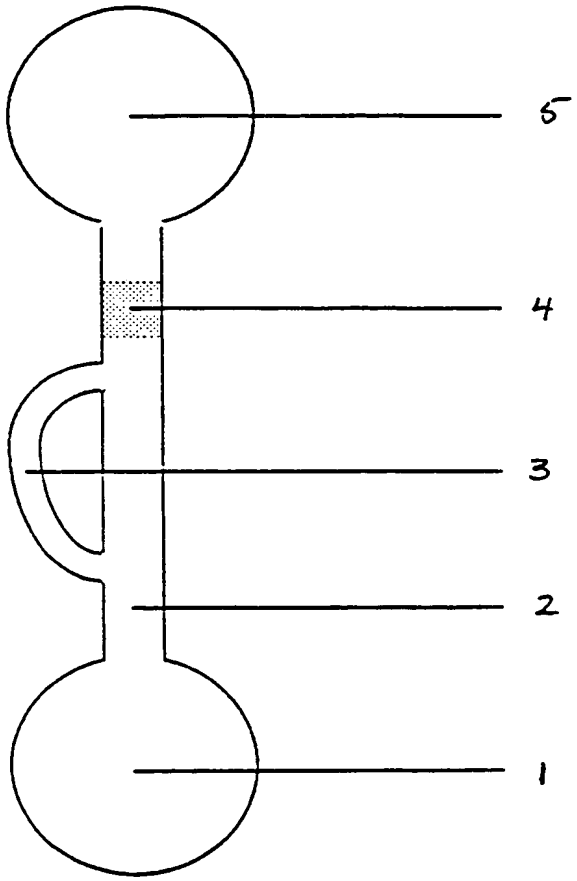
21. A method to assay and record a tissue/fluid sample comprising;

i) applying a sample to at least one sample application well of an assessment device according to Claims 1-20;

ii) mixing said sample with at least primary assay reagents; and

iii) recording the data from i)-ii) via the recording part.

22. A kit comprising an assessment device according to any preceding claim comprising an assessment device, assay reagents and, optionally, protective packaging for transport of the recording device to a processing facility.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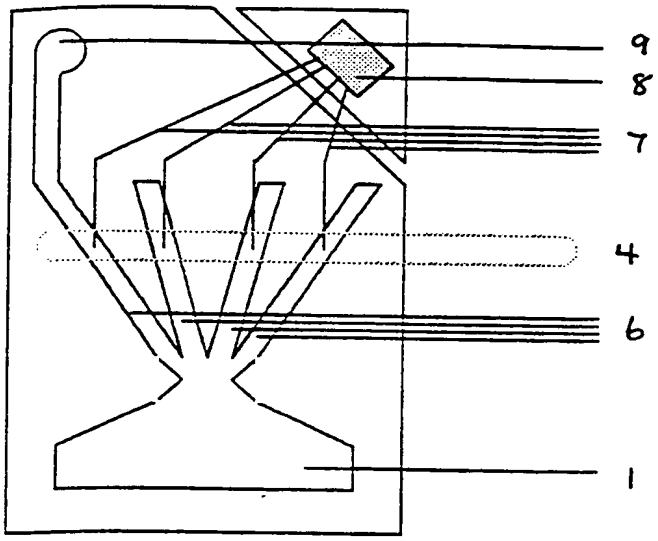
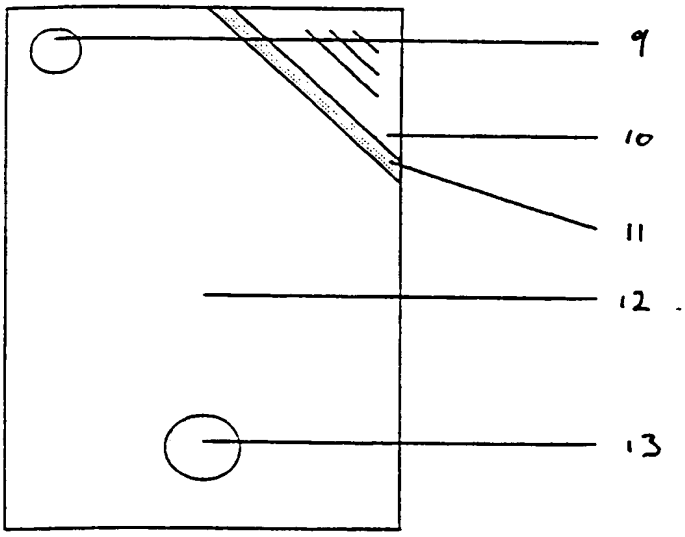
EXAMPLE - INTERNAL LAYOUT



EXAMPLE - EXTERNAL VIEW



INTERNATIONAL SEARCH REPORT

Inte. onal Application No
PCT/GB 98/00815

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01N33/558 G01N33/52 G01N33/543

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
A	US 5 182 191 A (FAN EUGENE ET AL) 26 January 1993 see abstract; figures	1,2,7-9
A	US 4 803 170 A (STANTON THOMAS H ET AL) 7 February 1989 see abstract; claims 9-11	1
A	WO 95 06240 A (METRIKA LAB INC) 2 March 1995 see abstract; figure 2	1,5

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents

"A" document defining the general state of the art which is not considered to be of particular relevance

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 July 1998	09/07/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ceder, O

2

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte .onal Application No
PCT/GB 98/00815

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5182191 A	26-01-1993	AU 4497189 A	01-05-1990
		CA 2000580 A	14-04-1990
		WO 9003927 A	19-04-1990
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		EP 0722563 A	24-07-1996
		JP 9503581 T	08-04-1997
		US 5580794 A	03-12-1996

PATENT COOPERATION TREATY

From the
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To:

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	29.06.99
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
FP2290	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB98/00815	18/03/1998	19/03/1997

Applicant
JACKSON, James Richard

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. (+49-89) 2399-0 Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Digiusto, M Tel.(+49-89) 2399-8162

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
FP2290		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 98/00815	18/03/1998	19/03/1997
Applicant		
JACKSON, James, Richard		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. [ ] **Certain claims were found unsearchable** (see Box I).

2. [ ] **Unity of invention is lacking** (see Box II).

3. [ ] The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
   - [ ] filed with the international application.
   - [ ] furnished by the applicant separately from the international application,
     - [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
   - [ ] Transcribed by this Authority

4. With regard to the **title,**
   - [X] the text is approved as submitted by the applicant
   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   - [X] the text is approved as submitted by the applicant
   - [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:

   Figure No. _____
   - [ ] as suggested by the applicant.
   - [ ] because the applicant failed to suggest a figure.
   - [ ] because this figure better characterizes the invention.

   [X] None of the figures.

PATENT COOPERATION TREATY

REC'D 05 JUL 1999
WIPO PCT

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
FP2290		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB98/00815	18/03/1998	19/03/1997
International Patent Classification (IPC) or national classification and IPC G01N33/558		
Applicant JACKSON, James Richard		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07/10/1998	29.06.99
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. (+49-89) 2399-0 Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer Goetz, M Telephone No. (+49-89) 2399 8697

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB98/00815

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-13 as originally filed

Claims, No.:

1-19 with telefax of 10/05/1999

Drawings, sheets:

1/2,2/2 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims 1 - 19
	No:	Claims
Inventive step (IS)	Yes:	Claims 1 - 19
	No:	Claims
Industrial applicability (IA)	Yes:	Claims 1 - 19
	No:	Claims

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Claim 1 on file incorporates the technical features of claims 1, 7, 9 - 11 and elements according to page 12, line 7 - page 13, line 7 and Figs. 1 and 2 as originally filed; the amendments do not therefore go beyond the content of the application as originally filed.

2. None of the available documents of the prior art neither discloses nor suggests the assessment device according to claim 1 comprising an assay part connected to a detachable device recording and storing the assay results of a sample applied to the assay part.

   The claimed two-part device is particularly suited for field use when no immediate medical advice is available. The assay data recorded and stored by the recording part can be electronically transmitted to a hospital or a remote health care institution for further evaluation and decision.

   The invention set forth in claim 1 and dependent claims 2 - 17 therefore meets the requirements according to Art. 33(2) and (3) PCT.

   This also applies to the method and the kit of claims 18 and 19, both making use of the assay device of claims 1 - 17.

CLAIMS

1. An assessment device comprising a first part adapted to undertake an assay wherein said part comprises at least one sample application well, in fluid connection with at least one primary conduit;wherein either, or both, of said well and said conduit contain material(s) for sampling a fluid sample; and a test ready indicator whereby a user can determine when a sample has been suitably assayed; and a second part which is a detachable recording device adapted to store information relating to at least to said sample after said assay has been completed and which is in data communication with said first part for storing assay results.

2. An assessment device according to Claim 1 wherein said assessment device and/or recording part is selectively sized and shaped to facilitate handling and transport of same to a processing facility.

3. An assessment device according to Claims 1 or 2 wherein said recording part is adapted to facilitate the transfer of data via electronic means.

4. An assessment device according to Claims 1-3 wherein said recording part is in retro-fit form.

5. An assessment device according to Claims 1-4 wherein said recording part is a microchip or a micro processor.

6. An assessment device according to Claims 1-5 wherein said recording part is a photographic recording means.

7. An assessment device according to Claims 1-6 wherein said assay part is characterised by multiple sample application wells.

8. An assessment device according to Claim 7 wherein at least one of said sample application wells is impregnated with material(s) for assaying a fluid sample.

9. An assessment device according to Claim 7 or 8 wherein said primary conduit contains reagents suitable for diluting said sample fluid.

10. An assessment device comprising a primary conduit according to Claims 7-9 wherein said primary conduit is suitably sized to facilitate capillary flow of said sample fluid therethrough.

11. An assessment device according to Claims 7-10 wherein said assay part is provided with at least one secondary conduit which is in fluid connection with one or more of said sample application wells.

12. An assessment device according to Claim 11 wherein said secondary conduit is suitably sized to facilitate capillary flow of said sample fluid therethrough.

13. An assessment device according to Claims 11 or 12 wherein said secondary conduit contains assay reagents.

14. An assessment device according to Claim 13 wherein said assay reagents are of a different nature to the assay reagents in the said primary conduit.

15. An assessment device according to Claim 14 wherein said assay reagents are compatible with the assay reagents of the primary conduit so as to provide, in total, for the complete and selected assaying of said

fluid sample as it flows through either or both primary and/or secondary conduits.

16. An assessment device according to Claims 1-15 wherein said assessment device includes at least one control or calibration means.

17. An assessment device according to Claims 1-16 wherein said assay part is provided with at least one detection zone to facilitate detection of the product(s) and/or responses of an assay.

18. A method to assay and record a tissue/fluid sample comprising;

i) applying a sample to at least one sample application well of an assessment device according to Claims 1-17;

ii) mixing said sample with at least primary assay reagents; and

iii) recording the data from i)-ii) via the recording part.

19. A kit comprising an assessment device according to any preceding claim comprising an assessment device, assay reagents and, optionally, protective packaging for transport of the recording device to a processing facility.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

16. FEB 99

To:

MARKGRAAF PATENTS LIMITED
The Crescent
54 Blossom Street
York YO24 1AP
GRANDE BRETAGNE

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	12. 02. 99
Applicant's or agent's file reference: FP2290	**REPLY DUE** within **3 month(s)** from the above date of mailing

International application no.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB98/00815	18/03/1998	19/03/1997

International Patent Classification (IPC) or both national classification and IPC
G01N33/558

Applicant
JACKSON, James Richard

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This report contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and / or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 19/07/1999

Name and mailing address of the international preliminary examining authority

European Patent Office
D-80298 Munich
Tel. (+49-89) 2399-0, Tx: 523656 epmu d
Fax: (+49-89) 2399-4465

Authorized officer / Examiner
Goetz, M

Formalities officer (incl. extension of time limits)
Hebert, W
Telephone No. (+49-89) 2399-8161

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

Description, pages:

1-13 as originally filed

Claims, No.:

1-22 as originally filed

Drawings, sheets:

1/2-2/2 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 - 7, 19 - 22
Inventive step (IS)	Claims	1 - 18
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

Re Item I

Basis of the opinion

The examination is being carried out on the **following application documents**:

Description, pages:
1-13 as originally filed

Claims, No.:
1-22 as originally filed

Drawings, sheets:
1/2-2/2 as originally filed

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Having an extremely broad wording, present claims 1 and 6 encompass assay setups of the prior art wherein any assay device (e.g. fluorometric, chromatographic, DNA sequencing or electrophoretic) is coupled to an ordinary PC (recording the data on the harddisk), a photo camera (recording the data on a film) or even a simple plotter (recording the data on paper). These recording parts are of course detachable from the assay device (a PC or a plotter is attached via cables, a photo camera is usually fixed by screws).

   Claims 1 and 6 do not therefore meet the requirements according to Art. 33(2) PCT.

   A sufficiently small PC equipment (such as a notebook) or a photo camera connectable via cables, clamps or screws to any assay device meets all the requirements as set forth in claims 2 - 5 which do not therefore comply with Art. 33(2) PCT as well.

   In principle, having regard to the undisputably high degree of knowledge of such state of the art, the IPEA is not required to cite a specific proof thereof. However,

a few copies made from previously issued catalogues of analytical equipment manufacturers (Bio-Rad and Pharmacia Biotech) are joined to this written opinion, each showing analytical assay devices connected to a PC station.

2. The devices cited above also satisfy the requirements as set forth in at least claims 7, 19 and 20 (when referring to e.g. claim 1); moreover, the assay method of claim 21 (when referring to e.g. claim 1) and the kit of claim 22 (when referring to e.g. claim 1) is also anticipated by the method according to which samples are traditionally analysed when using the known devices cited above and kit formats in which the known devices are delivered to customers.

   Hence, claims 7, 19 - 22 do not meet the requirements according to Art. 33(2) PCT.

3. The preferred embodiments recited in claims 8 - 18 relate to features which appear to be commonly known as being present in e.g. traditional immuno- or chromatographic assays based on chemiluminescent or fluorescent detection; assuming that the act of recording the corresponding assay data by means of e.g. a PC or a photographic recording has not already been carried out previously, the application of such act to known assays cannot be considered to involve an inventive step.

   Claims 8 - 18 do not therefore meet the requirements according to Art. 33(3) PCT.

4. It would appear that the IPEA can only consider the possibility of issuing a positive opinion in the case that the claims are properly recast to describe what is displayed e.g. in Fig. 2/2.